REMARKS

Claims 21-23 are pending in this continuation application. No claims have been cancelled. No claims have been added. Claim 21 has been amended.

Claims 21-23 have been rejected under 35 U.S.C § 112, first paragraph, as being non-enabled by the specification. It is the Examiner's view that the specification is enbabling for only reducing the risk of cervical dysplasia or cervical carcinoma in a subject, not for treating or preventing these disorders. In particular, the Examiner objects subparagraph (iii) of claim 21. As noted in the previous Response to Office Action, applicants do not agree with the Examiner's view regarding this issue. However, in an effort to move prosecution along in this case the claims have been amended, as set forth above, to address the rejection issued under § 112. In view of these claim amendments, applicants believe that the rejection has been traversed.

Applicants advise the Examiner that the amendment to suparagraph (iii) discussed above was made earlier in the prosecution of this application, i.e., in the Response filed on December 20, 2004. However, the amendment was inadvertently omitted in the Response to Non-Compliant Amendment filed on March 28, 2005. Accordingly, claim 21 again stands amended as in the Response filed on December 20, 2004.

Claims 21-23 have been rejected under 35 U.S.C. § 103(a) as being upatentable over Schubring in view of Bamji et al., US Patent No. 5,254,572 (Serfontain), Bielenberg, Harper et al., Check and Drug, Facts and Comparisons (1994). Applicants submit that these references, taken either alone or in combination, fail to teach or even suggest the claimed invention.

Schubring (complete translation included in the IDS being filed herewith) provides an overview of contraceptive products and their use. Schubring lists in Table 5 a number of contraceptive products commercially available in Germany. Some of these products include vitamins and/or minerals in the hormone-free tablets typically included in a contraceptive pill pack. One of the listed products, Norlest 28 Fe, includes seven hormone-free tables that include iron, pyridoxine and folic acid. This reference does not teach daily administration of folic acid by combining folic acid with a contraceptive hormones in a single dosage form. If fact, this reference teaches away from the claimed invention, insomuch as Table 5 of

Schubmg also lists Norlest 21 which does not include any hormone free tablets and, therefore, does not include any vitamin or mineral supplementation at all.

Bamji alos suggests that intermittent vitamin supplementation can be achieved by including vitamins in the non-hormone tablets in each contraceptive pill package. The reference does not teach or suggest daily administration of folic acid by combining folic acid with an oral contraceptive in the same dosage unit. Thus, Bamji fails to provide a method of administering folic acid that provides an adequate level of folic acid for those women who accidentally become pregnant while taking oral contraceptives. The '572 patent likewise fails to teach or suggest a method for the chronic, daily administration of folic acid. The '572 patent is concerned with administration of B6 vitamins and suggests that these vitamins can be included in oral contraceptive tables. The reference shows no appreciation of the risks of cervical dysplasia and cervical carcinoma for women who accidentally become pregnant while taking oral contraceptives, or the present method of reducing those risks by combining folic acid and oral contraceptives to provide for chronic, daily folic acid administration.

The Examiner cites Bielberg as disclosing that oral contraceptives can induce folic acid and vitamin B deficiency. Harper et al. is cited for the teaching that folate depletion is a risk factor for cervical dysplasia, and Check is cited for disclosing that folic acid supplementation may help reduce the risk of cervical cancer in women taking oral contraceptives. Finally, Drug Facts and Comparisons is cited for disclosing that the folic acid recommended daily allowance for adults is 400 micrograms.

The Examiner admits that the combination of these references fails to disclose a method of for reducing the risk of cervical dysplasia or carcinoma by administering in a single dosage form the combination of an oral cotraceptive and folic acid. Yet, the Examiner argues that this combination of seven references "amply suggests" such a method. However, none of the cited references, either alone or in combination, suggests any appreciation for the risk of cervical dysplasia and cervical carcinoma that results from the fact that women taking oral contraceptives can and do accidentally become pregnant while taking contraceptives. When such accidental pregnancies occur, women who have been taking oral contraceptives may very well have insufficient levels of folic acid to reduce the risks of contracting the specified disorders.

There is simply nothing in the combination of references relied on by the Examiner which would motivate the skilled person to provide the claimed method of administering folic acid to insure that women who are taking oral contraceptives, and yet can become pregnant, have adequate folic acid levels. This motivation is provided only by applicants' own teachings. Such hindsight reconstruction of the invention is clearly impermissible.

In view of the foregoing, applicants submit that the claims are in condition for allowance and favorable action is requested at the earliest possible date.

Applicants hereby petition for a one-month extension of time to respond to the outstanding Office Action. Please charge the fee required for this extension, and any other fees that may be required in connection with the filing of this Response, to Deposit Account No. 10-0750/ORT-1316/JSK.

Should the Examiner have any questions regarding this Response, please contact the undersigned attorney at the telephone number listed.

Respectfully submitted,

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